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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,424	05/23/2001	Victor M. Markowitz	4010US (111944-0015)	8455

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,424

Applicant(s)

MARKOWITZ, VICTOR M.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,16-21,24-28,35 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,16-21,24-28,35 and 37-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: ArrayDB database schema.

DETAILED ACTION

1. Applicants' arguments filed August 30, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 2-15, 22-23, 29-34, and 36 has been acknowledged.
3. Claims 1, 16-21, 24-28, 35, and 37-41 are examined on the merits.

CLAIM REJECTIONS - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 16-21, 24-28, 35, and 37-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ermolaeva et al. (1998).

RESPONSE TO ARGUMENTS

6. Applicant's arguments directed the cited prior art of Eckman et al. alone, or in combination with Schena et al. have been fully considered. The rejection directed to Eckman et al. and Schena et al. has been withdrawn. The newly applied prior art has been necessitated by claim amendments.

BASIS FOR PRIOR ART REJECTION

7. Ermolaeva et al. discloses a method for data management and analysis of gene expression data from microarrays. The method of Ermolaeva et al. comprises the ArrayDB system wherein gene expression data is stored in a relational database (Abstract etc. and page 20, column 1, Box 1), as in instant claim 1, lines 1-5; claim 21, lines 1-6; and claim 35, lines 1-6.

8. Ermolaeva et al. discloses a complete relational schema of the database is available on request (Figure 2). The authors have provided the PTO a copy of the schema upon the examiner's request. The citation of the Array DB Software Schema is not being used as prior art, but only to expand on the inherent characteristics of said relational database. Further, the limitation of "separate databases" has not been specifically defined in the instant specification. Therefore, the relational database of Ermolaeva et al. comprising separate databases (tables) is consistent with the required limitation. For example, the adb_CALC_INTENSITY_99 relational table contains sample data (sample database), UniGene and NonUniGene relational tables contain gene annotation data (annotation database), as in instant claim 1, lines 6-7 and 20-23; claim 21, lines 7-9 and 22-25; and claim 35, lines -8.

9. Clone information stored in the ArrayDB is extracted from UniGene (for example, sequence definition and accession number) (known standardized identifier). However, the design accommodates addition of newly addition of newly isolated clones for which accession numbers or meaningful names are not yet available (unknown standardized identifier). ArrayDB automatically scans a directory for new intensity data (expression level) (page 20, column 2, last paragraph). The disclosure of newly isolated clones has been

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reasonably construed as sample data directed to genomics. The gene fragment classification cited above is consistent with the disclosure for said classification in the instant specification (page 8, last paragraph), as in instant claim 1, lines 8-19, claim 21, lines 10-21; and claim 35, lines 9-20.

10. The Web-based user interface to the ArrayDB system supports database queries which allows retrieval of distinct types of information ranging from clone data to intensity data to analysis results. ArrayDB provides hyperlinks to other databases such as dbEST, GenBank, UniGene, or KEGG (page 21, column 1, lines 5-16), as in instant claim 1, lines 24-27; claim 21, lines 26-30; and claim 35, lines 20-25.

11. The ranking number is overlaid on the image for clones that have satisfied the query criteria wherein the ranking is according to ratio value. The ArrayViewer generates a cluster report (gene set). The MultipExperiment view supports analysis data from multiple experiments (sample sets) (page 21, column 2, Data Analysis §, and Figure 3), as in instant claims 16, 24, and 37.

12. ArrayViewer comprises textboxes for specifying call value thresholds based on two fluorescent probes (pair) for identifying gene sets being present and absent within the sample set as indicated by the “boxes” and ranking gene signature by ascending ratio value (pages 21-22, Data Analysis §, and Figure 3), as in instant claims 17, 25, and 38.

13. ArrayDB via the MultipExperiment (workspace manager) provides the comparison of data over multiple experiments by comparing multiple samples of a particular type of tumour or over a time course to determine differential expression. For example, the reference (control) sample is cDNA prepared from yeast cells harvest at the first interval after

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inoculation (page 23, column 1, lines 3-18), as in instant claims 18, 19, 26, 27, and 39, and 40.

14. ArrayDB via the ArrayViewer allows users to select a range of expression ratios wherein ArrayViewer returns information on genes with expression ratios in said range. Further, the MultipExperiment returns clones with high or low ratios in an experimental series (page 22, column 1, lines 15-18, and column 2, first paragraph), as in instant claims 20, 28, and 41.

CONCLUSION

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

16. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

18. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the

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USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

19. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
11/27/04


MICHAEL P. WOODWARD
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11/29/04